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Lex Scripta Journal

# Patent Evergreening and Healthcare Equity: A Legal and Policy Analysis

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# Patent Evergreening and Healthcare Equity: A Legal and Policy Analysis

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**Abstract**
*Evergreening is a strategy that can be utilised to prevent generic completion by utilising patents on pharmaceutical products or processes. Getting a patent on a product that is not a novel invention but rather a straightforward modification of an already existing product is what this signifies. This prevents people from gaining access to drugs that are within their price range, which poses a significant risk to public health. An evergreening of patents poses a significant risk in the poor world, because only a small percentage of individuals have the financial means to purchase original patented medications. In light of this, the first section of this article provides an explanation of the concept of "evergreening," as well as the perspective of the TRIPS agreement on it. Additionally, the paper discusses the evergreening tactics that are regularly utilised by branded pharmaceutical corporations as a means of circumventing existing patent restrictions and the reduction of competition from generic pharmaceuticals.*

**Keywords**: *Evergreening, Patents, medicines, competition*.

## Evolution of Patent Laws in India

In India, it was difficult for the general populace to access the medicines needed for human treatment. These medications were primarily imported from other nations. Due to a shortage of "natural medications and considerable demand, prices are quite expensive. The local law was impacted by the external law. India had some of the highest drug prices in the world.

Patent law is crucial because it encourages technological innovation. By defending the rights of the innovators, it promotes scientific investigation and progress. Regularization and assistance with patent registration are provided by patent law. The primary goal of the development of patent law was to guarantee that innovation is unrestricted and to encourage people to continually innovate by providing protection for their creations. As a result, patent law is crucial because it safeguards innovators' rights. The value of patents is acknowledged on a global scale.

Promoting new scientific discoveries, cutting-edge technologies, and industrial progress was the main objective of patents. Under patent law, an inventor has the

exclusive right to use their patented products, however others may use them under certain conditions and for a charge.

In the past, the goal of patent protection was to encourage innovation and the transparent sharing of the details of new concepts. By providing a temporary monopoly on their use, patent protection encourages the sharing of ideas something that inventors may be reluctant to do for fear that someone else would copy their creation. The innovation is fully disclosed in the application that is available to the public.

**The inventor can recover the cost of inventing the innovation during the patent protection term by:**

- Enforcing the patent to exclude competitors, monopolising the market, and setting a high price
- Granting the invention to others under a licence in exchange for royalties.
- Filing a lawsuit for damages if a person or company violates the patent.
- Selling the invention to a third party

Patent protection is significantly more reliable than other types of intellectual property protection, such as copyright. Copyright just protects the method an idea is communicated; it does not prevent others from expressing the same idea in different ways.

Furthermore, using patents as a negotiating tool can be successful. If a Cooperation wishes to use a patent that is owned by another company but also has patents that the company may use, it may be able to negotiate a zero-sum contract or a reduced licencing fee.

One scientist's scientific discoveries influence and inform those of other scientists. Industries would stall if discoveries were kept a secret, therefore promoting dissemination is advantageous for society and business as a whole.

A patent gives the inventor the authority to produce, use, market, sell, and import the invention for the predetermined time. In other words, the patent holder has the exclusive authority to forbid or halt anyone from making use of the protected invention for commercial purposes. Without the permission of the patent holder, the innovation cannot be made, utilised, disseminated, imported, or sold for a profit. It safeguards against patent infringement, meaning that the original inventor can take legal action against any products that attempt to copy their invention or infringe on a patent that has already been issued.

Science would undoubtedly advance slowly if everyone kept their discoveries a secret. So encouraging people to disclose their discoveries appears to be an effective method to advance science and useful arts. However, letting others benefit from your discovery by sharing it with them is an excellent method to do so.

**CASE:- Issue of Basmati rice patent[1]**

India's most popular cereal, basmati rice, is renowned for its aromatic flavor. This rice has a fragrant flavor and is cultivated in the Basmati region of India. Although Indian farmers had been cultivating this rice for hundreds of years, a Texan corporation was granted a patent for a cross-breed that included American long-grain rice. Based on the firm's scent, cooking elongation of the grain, and chalkiness, the US awarded the corporation a patent. From that point on, the company has the right to penalise farmers for growing rice and prevent them from sowing the seeds for the crop the next year. This made India to realize and file a petition with scientific evidence in the United States Patents and Trademarks Office saying that most varieties of Basmati possess these qualities. The USPTO accepted the petition.

**The Patents Act 1970**

On April 20, 1972, the Indian Patents and Designs Act 1911 was replaced by the Patents Act 1970 and the Patents Rules 1972. The recommendations of the report of the Ayyangar Committee, which was led by Justice N. Rajagopala Ayyangar, formed the bulk of the Patents Act. One of the suggestions was to only permit process patents for inventions pertaining to chemistry, pharmaceuticals, and other life sciences.

Later, India signed on to a number of international agreements in an effort to enhance its patent system and catch up to the rest of the world. Joining the Trade Related Intellectual Property Rights (TRIPS) system was one of the important stages towards accomplishing this goal. Significantly, India also became signatory of the Paris Convention and the Patent Cooperation Treaty on 7th December 1998[2] and thereafter signed the Budapest Treaty on 17th December 2001.[3]

The present Indian position in respect of patent law is governed by the provisions of the Patents Act, 1970 as amended by the Patents (Amendment) Act, 2005 (hereinafter referred to as the Act) and Patents Acts Rules, 2006 (hereinafter referred to as the Rules). [4]

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1 "G. Krishna Tulasi and B. Subba Rao, A Detailed Study of Patent System for Protection of Inventions, published date-2008 Sep-Oct, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3038276/"

2 **Patent Cooperation Treaty on 7th December 1998**

3 **Budapest Treaty on 17th December 2001**

4 "Jaya Bhatnagar and Vidisha Garg,India,Patent Law in India,publishing date- 13 December 2007,https://www.mondaq.com/india/patent/54494/patent-law-in-india,"

**The Head Patent Office is located at Kolkata and its branch offices are located at Delhi, Mumbai and Chennai. Patent system in India is administered by the Controller General of Patents, Designs, Trademarks and Geographical Indications. Each office has its own territorial jurisdiction for receiving patent applications and is empowered to deal with all sections of Patent Act.[5]**

The Patents Act, 1970's provisions gave Indian residents the chance to create new methods. India's economy grew significantly as a result of this. Bulk drug producers took advantage of the possibility to produce medications in large quantities and sell them for less money.
The Patents (Amendment) Act, 2005 revised the Patents Act, 1970 to expand product patents to all technological fields, including food, medicine, chemicals, and microorganisms. The modification has resulted in the deletion of clauses relating to exclusive marketing rights" (EMR) and the introduction of a provision that permits the issuance of forced licences. Additionally, pre-grant and anti-post protest-related provisions have been included.

**Trips Compliance and Amendments**
The most extensive international agreement on intellectual property to date is the TRIPS Agreement, which went into effect on January 1, 1995[6]. The areas of intellectual property that it covers include: "copyright and related rights (i.e. the rights of performers, producers of sound recordings, and broadcasting organisations); trademarks, including service marks; geographical indications, including appellations of origin; industrial designs; patents, including the protection of new varieties of plants; layout designs of integrated circuits; and undisclosed information, including trade secrets and test data.

**The Agreement has three primary components:**
1. Standards The TRIPS Agreement establishes the basic standards of protection that each Member must offer in relation to the principal categories of intellectual property that are covered by the Agreement. The basic components of protection are defined as follows: the subject matter that is to be protected, the rights that are to be granted, the exceptions to those rights that are allowed, and the minimum amount of time that protection should last. The Agreement establishes these standards by mandating that the most recent versions of the substantive obligations of the main conventions of the WIPO, which include the Paris Convention for the Protection of Industrial Property (Paris Convention) and the Berne Convention for the Protection of Literary and Artistic Works (Berne Convention), must be adhered to. All of the principal

[5] "Jaya Bhatnagar and Vidisha Garg,India,Patent Law in India,publishing date- 13 December 2007,https://www.mondaq.com/india/patent/54494/patent-law-in-india"
[6] https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm

substantive articles of these agreements are incorporated by reference and thereby become duties under the TRIPS Agreement between TRIPS Member nations, with the exception of the provisions of the Berne Convention on moral rights. Articles 2.1 and 9.1 of the TRIPS Agreement include the relevant clauses. These articles are related to the Paris Convention and the Berne Convention, respectively. Secondly, the TRIPS Agreement imposes a significant number of extra requirements in situations where the pre-existing agreements were either silent or considered insufficient. For this reason, the TRIPS deal is occasionally referred to as a Berne and Paris-plus deal.

2. Enforcement The second primary set of provisions addresses domestic procedures and remedies for the enforcement of intellectual property rights. The Agreement establishes a number of general rules that apply to all methods for enforcing intellectual property rights (IPR). Additionally, it includes provisions regarding civil and administrative procedures and remedies, provisional measures, and special requirements related to border measures and criminal procedures. These provisions specify, in a certain amount of detail, the procedures and remedies that must be available in order for right holders to effectively enforce their rights.
3. Resolving disputes. The Agreement makes it so that disputes between WTO Members over the compliance of the TRIPS commitments are subject to the WTO's dispute settlement processes.

Furthermore, the Agreement establishes several fundamental principles, such as national treatment and most-favored-nation treatment, as well as some general regulations to ensure that procedural challenges in gaining or retaining intellectual property rights do not negate the substantive gains that should result from the Agreement. All Member nations will be subject to the requirements outlined in the Agreement, but developing countries will have a longer amount of time to implement them. In the case that a developing country does not currently offer product patent protection for pharmaceuticals, special transition provisions are in place.

The TRIPS Agreement is an agreement that establishes minimum standards, but it also empowers members to give more extensive protection of intellectual property if they choose to. Members are free to decide how to implement the terms of the Agreement in their own legal system and practice.

The system of intellectual property rights in India has undergone significant changes, beginning with the British colonial period and continuing until India's accession to the TRIPS Agreement in 1995. The intellectual property rights regulations that have been addressed have been in the context of the changing era of globalisation. The primary emphasis of IPR was the introduction of patent law

and the well-known case of ***Novartis v. UOI***, in which India's existing patent law was modified in accordance with the TRIPS Agreement. When it comes to the worldwide situation, Indian intellectual property rights (IPR) regulations are quite important. The Indian laws are nearly equal to the international intellectual property rights system.

In 1994, India and a number of other developing nations signed the TRIPs agreement, which required them to change their domestic intellectual property rights legislation within ten years. For a large part of the 1990s, the signing of the TRIPs agreement was a contentious issue in India, even as the country proceeded to slowly change its patent system in order to meet the more stringent intellectual property rights (IPR) standards that were outlined in the pact. India became fully compliant with the Trade-Related Aspects of Intellectual Property Rights (TRIPs) agreement on January 1, 2005, when it implemented its most critical requirement: enforcing product patents across all disciplines of technology". Because there are so many theoretically legitimate conjectures on both sides of the TRIPs debate, empirical research on its actual repercussions in India would provide valuable insight into the importance of enhanced IPR protection for developing countries. India has just lately experienced changes in the field of intellectual property rights (IPR), which is a fairly broad area of law. Although the Indian legislators passed these laws about a decade ago, their progress has only recently been observed[7]. Despite the fact that intellectual property rights (IPR) rules are not a new idea, they are still not "well-known among the general public. The primary approach to addressing these problems will be to investigate ways to inform or educate the general public.

India's position on the TRIPS agreement might be used as an example of how the coordinates of India's WTO stance may have shifted, but the underlying neorealist policy paradigm has not changed. India's strong opposition to TRIPS prior to 1989 is completely understandable when you consider the interests of its pharmaceutical industry. At that time, the industry was still in its early stages of technological development and needed a weak patent regime in order to thrive and grow. India's unexpected change of heart about TRIPS in 1989 has frequently been associated with economic pressures from the United States. India may have adjusted its course of action to accommodate the interests of the United States, which is an economic superpower, in order to secure favours in other areas that are in India's best interest. This would support our contention that India has consistently chosen a neorealist position[8].

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[7] Ray, Shovon Amit, Saha, Sabyasachi, Inida's stage at the WTO: Shifting Coordinates, Unaltered Paradigm, Centre for International Trade and Development, January 2009, p-12 available at http://www.jnu.ac.in/SIS/CITD/DiscussionPapers/WTO.pdf

[8] Ramani, Shyama V and others, The Biotech Segment of the Indian Pharmaceutical Industry in the Brave New Post-TRIPs World, Veena, IPR Protection and TRIPS Compliance, Issues and Implications, p-181

The Indian government did not begin to construct its patent legislation until the first phase of industrialisation was completed, which was at the beginning of 1960. The Paris Convention of 1883 was the oldest international intellectual property rights convention at the time, and most countries adhered to it until the middle of the 20th century. India was in the same situation. In 1970, the Indian government altered its patent rules as part of a policy experiment to determine if this change will encourage private investment in areas that are knowledge-intensive and driven by the market. The pharmaceutical sector was greatly affected by the IPR policy experiment. The Indian legislators made their patent rules so restrictive that pharmaceutical companies were able to create important medications, such as antibiotics, at a far lower cost.

**Patent Law in India**

Liberalization and globalization are characteristics of the modern world. As a result, several nations, including India, which must compete with other nations on the global market, have enacted economic reforms. A nation's development is greatly influenced by patent legislation. More so now that India must compete with wealthy nations like the United States in the World Trade Organization.

A patent is a legally binding document granted by the government to the inventor, granting them the sole authority to sell, produce, utilize, and import the invention for a specified duration after the concept is published. Patents are legally mandated to protect innovators by imposing restrictions on the individuals authorized to market their products on their behalf. The origins of the term "patent" can be traced back to ancient French, Latin, and English. The term "patentem" and "patente" originated in the late 13th century, denoting the concept of an open letter. The phrase acquired its present connotation during the 1580s when it was elucidated as a governmental authorization for the production and commercialization of a certain commodity.

In business, a patent is used to create, market, and sell a product. Patents are used for many of the things that consumers buy. A patent is typically valid for 20 years from the application date once it has been granted by the government. The document that grants a person or company the exclusive right to sell a product is an official government letter patent. Once the patent application has been filed and approved, the patent applicant or vendor may begin collecting royalties for their products.

A royalty is a sum of money given to a product's creator in exchange for the right to use it; it is intended to pay them for their labour.[9]

A producer of a television advertisement might do this by paying a songwriter royalties for the use of their music in the ad. Patents and royalties are often kept

[9] "What is Patent, https://blog.ipleaders.in/patent-law-2/ (last visited, 2:33pm 9th April)"

private by businesses using strong agreements and trade secrets, at least until the product is introduced to the market. Regardless of whether a provisional or complete specification is included in the patent application, the term of all Indian patents is twenty years, beginning on the date of filing. This means that the term begins on the date of filing. On the other hand, the twenty-year period commences on the date of the international filing (PCT) for applications that are submitted in accordance with the Patent Cooperation Treaty.

In principle, the owner of the patent has the sole right to prevent or hinder others from commercially exploiting the invention that has been patented. In other words, the protection afforded by a patent ensures that the invention cannot be manufactured, utilized, disseminated, imported, or sold by third parties without the permission of the registered owner of the patent. By giving innovators exclusive rights to profit from their ideas, the patent system hopes to inspire them to progress technology. Books, films, and works of art cannot be patented, but copyright law offers protection for these types of works.
Novelty and inventive step are fundamental concepts in patent law (or lack of obviousness). They grant the right to forbid anyone from using the innovation for the life of the patent from doing so, including independent creators of the same concept as well as copycats[10]. Therefore, a patent has the unique ability to be utilized to forbid others from using any kind of invention in their goods and services. Thus, a patent creates significant challenges for its rivals. This is why only industrial advances that are deemed to qualify as patentable inventions are granted patents, rather than all industrial improvements.

There were several obstacles that the general population of India had to overcome in order to obtain the necessary drugs for human treatment. In the majority of cases, these pharmaceuticals were brought in from other countries. In light of the fact that there is a lack of natural drugs and a significant demand for them, prices are fairly high. External laws had an effect on the local laws that were in place. Some of the most expensive pharmaceuticals in the world were sold in India.
The law governing patents is essential because it fosters the development of new technologies. It does this by protecting the rights of those who introduce new ideas, which in turn encourages scientific research and advancement. Patent law is responsible for providing regularization as well as assistance with all aspects of patent registration. Patent law was developed with the primary purpose of ensuring that creativity is unlimited and encouraging people to continue innovating by providing protection for their works. This was the major driver behind the formation of patent law. As a consequence of this, patent law is essential since it functions to protect the rights of innovators. There is widespread recognition of the importance of patents on a global scale.

[10] "Patents, https://www.wipo.int/patents/en/, (Last visited, 8:40pm 6th April)"

One of the primary objectives of patents was to encourage the development of new technologies, breakthrough scientific discoveries, and industrial advancements. The law about patents grants the inventor a monopoly on the use of their patented products, but it also allows others to use such products with the inventor's permission and for a price.

In the past, the purpose of patent protection was to encourage creative endeavors and the free disclosure of the particulars of ideas that were novel. A temporary monopoly on the use of an invention is granted by patent protection, which provides an incentive for the sharing of ideas. However, inventors may be reluctant to share their ideas because they are afraid that someone else will imitate their creation.

**Detailed information regarding the invention is included in the application that is available to the general public:**

1. By enforcing the patent to exclude competitors, monopolizing the market, and setting a high price, the inventor can recover the cost of inventing the idea during the period of time that the patent is for protection.
2. In exchange for royalties, granting the invention to other individuals under the terms of a licence.
3. If a person or company breaches the patent, you have the option of filing a lawsuit to seek damages.
4. Making the offer to sell the invention to a third party

The patent protection system is significantly more robust than other kinds of intellectual property protection, such as copyright. It is only the manner in which an idea is communicated that is protected by copyright; it does not prevent other people from expressing the same thought in different ways.

As an additional point of interest, patents are an efficient method of negotiation. It is possible for a Cooperation to negotiate a zero-sum contract or a lesser license payment" if it wishes to make use of a patent that is owned by another company but also possesses patents that the other company may utilize.

The findings made by one scientist have an impact on and provide information to the discoveries made by other scientists. If discoveries were kept a secret, industries would come to a halt; hence, fostering distribution is beneficial for society as a whole as well as for business.

A patent grants the person who invented the invention the right to manufacture, use, market, sell, and import the innovation for a period of time that has been established in advance. To put it another way, the person who has the patent has the exclusive ability to prohibit or prevent anyone from making use of the innovation that is protected for commercial purposes. In the absence of authorization from the patent holder, the innovation cannot be manufactured, utilized, distributed, imported, or sold for a profit. It provides protection against patent infringement, which means that the original creator has the ability to

pursue legal action against any items that attempt to imitate their innovation or infringe on a patent that has already been issued.

If every single person kept their findings a secret, there is no question that scientific progress would be sluggish. Therefore, it would appear that encouraging people to publish their discoveries is a successful strategy for advancing scientific research and the arts that are beneficial. On the other hand, one of the most effective ways to accomplish this is to share your finding with other people so that they can profit from it.

**Features of Patent Act:** [11]

Not only Product but also "Process can be patented under act:

1. Invention shall be useful, novel and something which is not obvious.
2. Shall be capable of getting used in Industry, if not then it may amounts to revocation of patent.
3. Invention shall be new and shall not form part of Section 3 and 4, which provide for exceptions of ideas which cannot be patented.
4. Term of patent – 20 years (can be renewed) (in some case it may also be upto 7 years)
5. Patent Examination can be conducted on request.
6. Both pre-grant and post-grant opposition is enabled.
7. Fast track mechanism shall prevail for disposal of appeals if any disparity exists.[12]
8. Values to protect integrity of Indian Constitution's various clause such as Article 51-A of fundamental Duties is also taken into consideration by nurturing and keeping nature and rich heritage of culture in mind. Hence Provision for protection of bio-diversity and traditional knowledge is specified in act.
9. Publication of applications after Eighteen months with facility for early publication enable getting patented rights as if it was registered from day if reasonableness of time is observed".

**Types of patents** [13]

To protect various types of inventions, various forms of patents are available. Competent innovators can use the various "patent application types to obtain the legal protection they require for their discoveries:

1. **Utility patent**

   Most people typically associate inventions covered by utility patents with the term "patent." A utility patent is a type of powerful form of protection that is a technical document that provides a detailed description of how a

[11] "Sonu Arvind Chaturvedi,Patent Law – Salient Features and Upgradation-Justice India ,Patent Law - Salient Features and Upgradation - E-Justice India (ejusticeindia.com)"

[12] "Patent Law in India, https://www.mondaq.com/india/patent/54494/patent-law-in-india , Last visited 9th April."

[13] "Daisy Jain, What is a patent, August 16, 2022, https://blog.ipleaders.in/patent-law-2/"

new device, method, or system works. This patent has protected a wide range of inventions, such as computers, pharmaceuticals, business processes, and brooms. The utility patent has a 20-year term.

Utility patent applications are the most frequent forms of patent requests received by patent offices worldwide. Such a patent covers a range of unique and generally useful techniques, devices, material compositions, and manufactured goods. These utility patent elements are described as follows: [14]

**Processes:** Processes are defined as any method or act of doing something, typically involving technical or industrial processes.[15]

**Compositions of matter:** A composition of matter utility patent type refers to the chemical compositions, including a mixture of ingredients and substances or new chemical compounds.

**Manufactures:** A manufacture is any product that requires undergoing a manufacturing process.

**Machine:** A machines utility patent includes anything that is primarily regarded as a machine – for instance, computers, refrigerators, air conditioners, etc.
A utility patent can be obtained for a new invention, but it can also be applied for in the event that an existing technique, equipment, materials, composition, or production is being improved in a novel and practical way.

2. **Design patent**
The ornamentation of a useful object is protected by this patent. For example, a design patent can protect a shoe's or a bottle's appearance. The illustrations or sketches that show the practical item's design make up the majority of the real paper. A design patent is infamously difficult to find since it has so few words. Recently, software companies have taken advantage of design patents to protect touchscreen device designs and other user interface elements. The invention's design needs to be both original and useful. The design patent duration is 15 years. The design of the product must be inseparable from the object in order to qualify for design patent protection. [16]The design patent is only given for, and hence only covers, the appearance of the object, even though the object and design should

[14] Daisy Jain, What is a patent, August 16, 2022, https://blog.ipleaders.in/patent-law-2/
[15] What Are The Different Types Of Patents? ,IPTSE, last seen,23-9-2022 ,https://iptse.com/what-are-the-different-types-of-patents/
[16] What Are The Different Types Of Patents? ,IPTSE, last seen,23-9-2022 ,https://iptse.com/what-are-the-different-types-of-patents/

match. The original Coca-Cola bottle design is an illustration of this kind of patent.

3. **Plant patent**

A plant patent covers novel varieties of plants developed through cuttings or other non-sexual methods, as the name implies. Genetically modified species are typically excluded from the scope of plant patents, which instead emphasize traditional gardening. Plant patents mostly concentrate on non-traditional horticulture. Similar to utility patents, plant patents are currently not allowed in India, yet you can file for one in Australia, the USA, and several other European nations. The plant patent duration is 20 years.

**Pre-requisites of getting a Patent**

**"Patents shall be granted for any inventions which are susceptible of industrial application (utility), which are new and which involve an inventive step (non-obvious)"- Art. 52(1) EPC[17]**

Discovering out about or revealing the existence of something that was previously unknown or unacknowledged is known as discovery. An invention is the making or constructing of something that did not previously exist.

An innovation will only be qualified for a patent award in India if it satisfies the requirements for patentability. To be deemed patentable, an innovation must satisfy all requirements that assess its eligibility for a patent grant from a variety of perspectives. While some of them are simpler to achieve than others, they are all equally important for assessing patentability.

**The prerequisites for patentability criteria are as follows:**

1) **Novelty [18]**

A product or method will only be considered an invention under the Patents Act if it is both inventive and innovative. Simply put, novelty refers to anything that is novel in comparison to the state it was in at the time the patent application's priority date. An innovation will be considered distinctive if it differs from the "prior art," which is what currently existing. For novelty analysis, previous art references are never combined; rather, uniqueness is always assessed in light of one specific prior art reference at a time. Even though it isn't stated expressly in the reference, general knowledge of the art may be included in a prior art citation. Numerous parts pertaining to inspection, anticipation, objection, and revocation involve novelty.

In patent law, the concept of novelty is a "manifestation of the principle that patent protection should be granted to only those inventions that are actually new. The phrase "novelty" refers to something that is "new in comparison to prior art."

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[17] Art. 52(1) EPC

[18] Novelty: An Indian Perspective, by Pankaj Musyuni (18 December 2017).

It is a condition that in order for an invention to be patentable, it must be in some way distinct from all published papers, known procedures, and goods that are currently on the market. To be eligible for a patent, the innovation in question must not have been made accessible to the general public prior to the submission of the application for the patent. Discovering something that has not been discovered by other people is the definition of an invention". Patents are a form of "quid pro quo" agreements. Therefore, the patentee is granted a monopoly over his invention as a result of this".

A definition that is assigned under section 2(1)(l) of the Indian Patents Act 1970 (hence referred to as "the Act") is used in India to determine whether or not an invention is a "new invention" (possesses novelty). This definition is used to determine whether or not an invention is considered to be novel. A "new invention is defined as any invention or technique that has not been predicted by publishing in any document or used in the country or elsewhere in the globe previous to the date of the filing of the application with complete specification. This definition is based on the fact that the term "new invention" was first used in the United States. To put it another way, the subject matter has not been in the jurisdiction of the public or been incorporated into the current state of the art.

Because of a lack of novelty or anticipation, the patent system does not grant patents to innovations that were revealed prior to the time that an application was submitted to the Patent Office. This is the reason why patents are not issued. The regime stipulates that a patent can only be awarded for an invention that is either novel or novel in nature. This is one of the conditions attached to the system. The term "anticipation" refers to the absence of anything new.[19]

2) **Inventive step**

"Is the approach obvious, and if it is not, what is the depth of the inventive steps taken by the inventor?" is the second question that arises when determining if a product or a technique is innovative. The obviousness of a solution is established by determining whether or not a person with average skills in the subject would have invented a similar innovation for the technical issue under identical conditions without being offered the solution.

In comparison to the other requirements for patentability, the need of an innovative step is the one that is the most difficult to describe and the most difficult to express consistently. According to the Indian Patents Act, the non-obviousness of creative steps and the technical advancement or economic value of the step are two considerations that are considered while judging creative steps.

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[19] "Indian Patent Act, 1970, Section 29(1)(l) https://www.hkindia.com/news_letter/article/1/Patent%20artile-1.html#:~:text=The%20concept%20of%20novelty%20in%20patent%20law%20embodies%20the%20principle,known%20techniques%2C%20and%20marketed%20products. Last visited 10th April 2024".

Subsection 2(ja) of the Patents Act provides a definition of creative steps. "*the characteristic of an invention that involves technological advancement or is of economic importance or both, as compared to existing knowledge, and invention that is not obvious to a person skilled in the art,*" is the definition of an innovative step that can be found in Section 2(ja) of the Patents Act.

It is essential that the creation reflects the originality of the innovator. The thing in question must be something that a skilled craftsperson would not anticipate. Imagine for a moment that an inventor designs a device with the purpose of resolving a technological issue. Another expert in the same field delivers the same answer by making use of his existing knowledge or by acquiring new information. Due to the fact that it was merely an idea or motivation, the technological solution that the inventor came up with will not be considered original in that particular scenario. In the case of *Biswanath Prasad Radhey Shyam*[20], which took place in 1978, the Supreme Court assigned a definition to the word "inventive step," and this definition is still utilised for inventive step analysis today.

One of the most important terms to use when discussing the creative step is "obvious." In addition, the creative step is frequently referred to as the "non-obviousness clause." According to the European Patent Office (EPO), this is defined as going beyond the expectations of technology rather than just taking the next natural step". For the purposes of the Act, a patent that was obtained in any other nation would not be considered "prior art to the invention."[21]

The case of ***Windsurfing International v. Tabur Marine*** [22]provided an explanation of a methodical technique to determining obviousness that is comprised of four discrete steps**:**[23]

a. "Determine the inventive idea that is contained inside the case suit.
b. As the priority date will be the date from which the objector to the patent would say that inventive step was evident, it is important to keep in mind that a person who is typically proficient but lacks imagination and has common broad knowledge of the art in question.
c. Using the spectacles of the aforementioned skilled person, identify any differences, if any, between the matter that is cited as being known or used and the alleged invention;
d. Finally, without taking into consideration the alleged invention, consider whether the differences would be seen by the aforementioned skilled person as leading obviously to the alleged invention or as indicating that a degree of invention would be required to obtain the invention".

The Intellectual Property and Appellate Board (IPAB) issued a decision in August 2013 that revoked the patent number 212695 [in the case Ajanta Pharma Limited

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[20] AIR 1982 SUPREME COURT 1444

[21] "A patent granted in US would not be a bar to a patent in India for the same invention."

[22] 1985 rpc 59

[23] "Windsurfing International v Tabur Marine 1985 RPC 59"

v. Allergan Inc. and Others]. In this decision, the IPAB established that a person must be "sufficiently skilled or knowledgeable of the art" and should not "merely be a person having ordinary skills in the art." It was also discovered in the judgement handed down by the Delhi High Court in the case of **Hoffman-La Roche Ltd. and Others v. Cipla. Ltd.**[24]

3) **Industrial application**

Patents Act, Section 2(ac), states that "the creation is a patent of being used or created in a sector." This provision was added in the year 2000. It suggests that in order for a product to be patentable, it must be useful. This is due to the fact that an invention cannot exist in a vacuum and must be applicable to all sectors. In order for a product to be considered industrially applicable, it must first be able to be made in a dependable manner and then have at least one use within a certain industry. In order for the industry to fulfil this criteria, it is necessary for them to implement a procedure. Users are not deemed to be honest if they are ambiguous, have a future-oriented perspective, make no particular statements, or are confused. In the same vein, the same thing happens when a product or process is used in a sloppy or untrustworthy manner.

In the case of *F. Hoffman-La Roche*, the court provided a comprehensive understanding of the term. It stated that re requirement necessitates an invention to have commercial use. Furthermore, the court stated that even if the invention for which an application is made is not in its final form, the patent can only be granted in situations where there is some commercial viability to the same invention. Therefore, the focus of this need is not on the product itself but rather on the potential; it must be sustainable from a business perspective.[25]

After analysing numerous Indian and foreign precedents regarding the utility or industrial application criteria, the Delhi High Court highlighted that an innovation must be commercially viable in a case involving **Cipla vs Roche**. Commercial development need not be proven, but commercial use is essential. Fundamentally, the innovation must to fulfil the purpose specified in a patent specification and have a use in the real world. There won't be anything else needed to prove an invention's usefulness for patentability.

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[24] "S.S. Rana & Co. Advocates ,India: Understanding Inventive Step In Patent Applications In India 01 April 2019, https://www.mondaq.com/india/patent/795108/understanding-inventive-step-in-patent-applications-in-india )"

[25] "The requirements of Industrial Applicability Under The Indian Patent Law,INTEPAT, January 19, 2021, https://www.intepat.com/blog/patent/the-requirements-of-industrial-applicability-under-the-indian-patent-law)"

In the case of "*Bishwanath Prasas Rradhe Shyam v. Hindustan Metal Industries* (PTC (suppl) (1) 731 (SC)", the Supreme Court of India made the following decision[26]:

- The purpose of patent law is to promote scientific research, the development of new technologies, and the advancement of industrial growth. The disclosure of the invention at the Patent Office is the price that must be paid in order to receive a monopoly. Once the monopoly time has expired, the innovation will be released into the public domain.
- Patent law is based on the fundamental idea that a patent can only be granted for an invention that is both newly invented and useful. In order for a patent to be considered legitimate, it is necessary for the inventor to have made the discovery themselves, as opposed to merely verifying what was already known prior to the date of the patent.
- An improvement on something that has been known before or a mix of several things that have already been known must be something that is more than a simple improvement made in a workshop, and it must independently pass the test of invention or inventive step in order to be patentable.
- It must create a new outcome, a new article, or an article that is either better or cheaper than the one that was before. "Invention" must be incorporated into the new subject matter as compared to the existing one. A simple collection of more than one, integers, or things that does not involve the exercise of any inventive faculty is not sufficient to qualify for the granting of a patent.

**Patent -Evergreening and Its Impact**

Evergreening patents on medical products extending the lifespan of patents that are about to expire is an "abuse of the intellectual property system", an HIV activist told the World Health Organization's (WHO) Fair Pricing Forum.

Meanwhile, an industry representative laid out her "company's value-based, country-specific approach to improving access to medicines, providing an example of how it had improved access to cancer medicine in Nigeria. Ukraine-based Sergiy Kondratyuk, who works for the International Treatment Preparedness Coalition, said that evergreening is pervasive and a barrier to lower medicine prices[27].

The word "evergreening" is an informal term that refers to the practice of making a minor adjustment to an existing product and then claiming that it is a new innovation. This practice has developed in specific jurisdictions. The coverage or protection provided by the supposed new innovation is subsequently utilised to extend the patentee's exclusive rights over the product, which prevents competition. For example, in the pharmaceutical industry, brand-name businesses

[26] AIR 1982 Supreme Court 1444

[27] https://healthpolicy-watch.news/evergreening-medicine-patents-is-abuse-of-intellectual-property-system/

patent "new inventions" that are actually only little changes to existing pharmaceuticals. This practice is known as "evergreening."[28]

In light of the aforementioned, what would be considered "trifling" would effectively determine if there is an attempt to evergreen a patent or whether it is eligible to be patented.[29] Therefore, the door is not completely closed on patenting an existing invention with minor adjustments. To comprehend what is considered a minor alteration, we must now focus on the terms of the Act.

## Concept of Patent Evergreening

Evergreening denotes the practice of filing new patent applications related to the original innovation. This allows patent holders to prolong the protection of their inventions against competitors for an extended duration. Typically, the approach involves the submission of several subsequent inventions that are based on the original patent. This is executed to enhance the protection of the innovation". The objective is to eliminate any loopholes that rivals can exploit to bypass the original innovation and produce a competing product or service without infringing the patent.

In India, patents are granted for a duration of twenty years, contingent upon the complete payment of annual fees. Upon the expiration of the patent term for an invention, the invention is deemed to enter the public domain. This implies that the innovation may be produced, marketed, or imported by any individual, corporation, or entity without limitation. Conversely, there are occasions when patent holders, typically pharmaceutical corporations, endeavor to maintain their monopoly on the innovation even after the patent has lapsed. They accomplish this by filing a new patent application for small alterations made to the original concept. This prohibits any other corporation from producing or commercializing the invention.

## Advantages

- Longer patent life: It offers more protection for inventions for a longer length of time. This is particularly advantageous for businesses that have made significant investments in research and development and wish to safeguard those assets from competitors for as long as feasible.
- Keep making money: Evergreening can also help businesses keep their market share by stopping other companies from coming into the market with products or services that are similar.
- Legal protection: Evergreening can also bring other legal benefits, such as greater damages in infringement instances or a drop in licensing prices due to increased protection.

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[28] https://www.lexology.com/library/detail.aspx?g=aacfd802-52e1-4468-b71e-6a6a2d2c513b

[29] Roger Collier, Drug patents: the evergreening problem, CMAJ. 2013 Jun 11; 185(9): E385–E386. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3680578/

Patent evergreening denotes the tactical exploitation of the patent system by pharmaceutical firms to prolong their monopoly over a product beyond the initial 20-year patent duration. This frequently entails implementing minor or negligible alterations to a medication, which do not substantially enhance its therapeutic efficacy but enable the corporation to get additional patents[30]. These tiny modifications can obstruct the entry of generics or biosimilars into the market, hence sustaining elevated pricing and regulating market share.
The primary mechanisms of patent evergreening are[31]:

**Examples:**

- Extended-Release (ER) Formulations: Modifying a drug's formulation from an immediate-release (IR) tablet to an extended-release (ER) or controlled-release variant can obtain a new patent. The ER formulation may permit reduced dosing frequency, offering convenience to patients; nevertheless, it may not consistently deliver significant additional therapeutic advantages. Nevertheless, it may be promoted as a "enhancement" and assigned a new patent.
- Transdermal Patches: Certain pharmaceuticals are reformulated into transdermal patches, facilitating drug absorption through the dermis, thereby providing an alternative delivery technique without necessarily enhancing the medicine's clinical efficacy.

1. **New dosage strengths**- Pharmaceutical companies have the ability to file fresh patents for an already marketed medicine based on changing strengths or dosages. This enables them to prolong patent protection, even if the active component and its composition do not change.[32] This strategy can be used to create more monopolies on different versions of the drug, such as a higher or lower dose, without delivering any significant improvements in the treatment's clinical advantages.

**For example:**

- A firm may patent a greater or lower dose of a drug after the original patent expires. For example, a corporation could patent a 100 mg version of a drug after the original 50 mg patent has expired. The release of generic versions of the original strength may be delayed due to the patent extension on this new dose.
- The antidepressant medication Prozac (Fluoxetine) had its exclusivity extended by patenting new doses of the same molecule. This makes it more difficult for generic versions of the original Prozac to be sold.

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[30] Abbasi, K. (2016). Patent Evergreening in the Pharmaceutical Industry. British Medical Journal, 354, i4887.
[3131] https://iaeme.com/MasterAdmin/Journal_uploads/IJIPR/VOLUME_14_ISSUE_2/IJIPR_14_02_003.pdf
[32] Eisenberg, R. S. (2013). Patent Evergreening and the Pharmaceutical Industry: From Monopoly to Competitive Market. Yale Journal on Regulation, 30(2), 481-507

- Celebrex (Celecoxib) is a painkiller that has had patents filed for new dosing strengths. This has extended the period of time that the drug is exclusive and has postponed the release of generic alternatives.

**Analysing Relevant Patent Act Provisions**

Before we can analyse the part of the Act that addresses evergreening, we first need to understand what can be patented". According to Section 2(j) of the Act, a patent can only be granted for an invention if it is a "*new product or process involving an inventive step and capable of industrial application.*"[33] The Act further defines a 'inventive step' under Section 2(ja) as "*a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art*".

**Therefore, when the aforementioned sections are read together, a product must meet the following criteria in order to be considered an invention[34]:**

i. it must be new;
ii. it must be capable of being made or used in an industry; and
iii. it must come into being as a result of an invention that has a feature that
   a. entails technical advance over existing knowledge; or
   b. has an economic significance; and
   c. makes the invention not obvious to a person skilled in the art.

At this point, even if an invention reaches the criteria described above, it may still not be eligible for a patent if it falls under the provisions of Section 3 of the Act[35]. Section 3 specifies "what does not qualify as an invention according to the Act. This is where we discover the anti-evergreening provision, which is included in Section 3(d) of the Act and is copied below:

*"d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.*

Explanation.—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy"

Section 3(d) clearly states that it applies in situations where there is a "mere discovery" of a new property or new use of a known material, or the "mere use"

[33] Section 2(j) of the Patents Act, 1970
[34] Novartis AG v Union of India, (2013) 6 SCC 1
[35] Section 3 of the Patents Act, 1970

of a known process, machine, or apparatus. Unless it leads to an increase in the effectiveness of the known drug, or unless the known procedure results in a new product or uses at least one new reactant. As a result, Section 3(d) must be seen as a positive clause that acknowledges incremental innovation while also warning that the incremental steps may be so little at times that the resulting product is no different from the original.

It is necessary to evaluate each situation individually in order to ascertain whether or not a patent for a specific invention would be affected by Section 3(d), as this is contingent on the characteristics of the product or process[36]. Of course, the standards that apply to this evaluation will differ depending on the industry to which the product or process belongs.

The Delhi High Court, in the case of ***Cipla Ltd v. F. Hoffman-La Roche Ltd***[37]., ruled that Section 3(d) of the Indian Patents Act allows for a range of derivatives of known substances, including a compound that is not active on its own but is metabolised in the body to form an active drug, which is known as a prodrug. This ruling was made in the context of pharmaceuticals, which have generated the most jurisprudence in this field in India. For example, chloramphenicol succinate ester is used as an intravenous prodrug of chloramphenicol because pure chloramphenicol does not dissolve in water. Another example is a composition, which is a combination of two or more active ingredients or a combination of a pharmaceutical carrier with a compound that has not been used as a drug before. A third example is a drug delivery system, which is a composition that has constituents that allow it to be administered in a specific way. If the product improves upon the proven effectiveness of the product, it would not be termed "evergreening" and would be eligible for a patent. When it comes to drugs, this effectiveness should be evaluated based on the product's "therapeutic efficacy."

In the case of ***Communication Components Antenna Inc. v. Ace Technologies Corp***[38]., the Delhi High Court ruled that an objection to the suit patent was invalid under Section 3(d). The court stated that the provision does not apply in cases where newer technology is developed and better efficiency is achieved based on existing technology. This ruling was made in the context of technological innovations, where the suit patent was based on known elements but its novelty lay in the resultant increase in efficiency". In this example, the increase in efficiency was assessed by measuring the increase in the effectiveness of the beams that were emitted by the antennas that were the subject of the patent lawsuit.

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[36] Section 3(d) of the Patents Act, 1970
[37] 2015 SCC OnLine Del 13619
[38] 2019 SCC OnLine Del 9123 : (2019) 79 PTC 270

**The Novartis case: Indian judiciary's opposition to patent evergreening**

The recent verdict by India's Supreme Court regarding the Novartis case has highlighted the issue of patent evergreening. Novartis, a “Swiss pharmaceutical corporation, aimed to secure a patent for an enhanced formulation of its cancer medication Gleevec, asserting its superior efficacy in combating leukaemia. India's patent legislation, particularly Section 3(d) of the Patents Act of 1970, forbids evergreening by disallowing the issuance of patents for trivial alterations of existing patents.

Novartis contested the legitimacy of Section 3(d) in court, asserting that it violated international treaties, including the TRIPS (Trade-Related Aspects of Intellectual Property Rights) agreement and Article 14 of the Indian Constitution.

i. Assessing the novel formulation of the established invention and its effectiveness regarding pharmacological characteristics;
ii. Analysing the pharmacological properties of the prior and novel formulations of the established compound;
iii. Incorporating comparative data on enhanced efficacy through affidavits or in the patent application process;
iv. Excluding physicochemical factors such as "superior flow characteristics," "enhanced thermodynamic stability," and "decreased hygroscopicity" when evaluating therapeutic efficacy;
v. The therapeutic efficacy of medications should be evaluated with strict precision.

**Impact of Patent Evergreening**

In the pharmaceutical sector, research expenditures are quantified in the billions of dollars. Of every thousand potential treatments assessed, it is estimated that merely four to five advance to clinical trials, with only one ultimately receiving approval for commercialization. Through appropriate pricing systems, pharmaceutical businesses can recuperate research costs and generate revenues for shareholders from individuals utilizing copyrighted medications. Pharmaceutical companies secure exclusive marketing rights through the patenting of their developed medications. Globally, medicine patents and their related exclusive marketing rights are conferred for a period of twenty years. Throughout this interval, no other pharmaceutical entity is authorized to p roduce or promote the identical medication. Upon the patent's expiration, other companies are authorized to develop and market the medication; the resulting products are termed generic versions.

In the early 1970s, Indira Gandhi's government implemented the Indian Patents Act to facilitate greater access to affordable drugs for the underprivileged population. The Act stipulates that patents for processes will be acknowledged, whereas patents for items will not be acknowledged. India would not issue patents for specific pharmaceuticals, but rather for the manufacturing processes

employed to generate those medications. Consequently, Indian pharmaceutical businesses were able to manufacture the identical medication by utilizing alternative production methods, commonly known as reverse engineering. Given that Indian firms allocated minimal funds to the research and development of new pharmaceuticals, it became possible to provide new treatments to the nation at affordable prices.

The committee on patent legislation, created by the government and chaired by R. A. Mashelkar, former chief of the Council for Scientific and Industrial Research, endorsed the granting of patents for all incremental advancements in medicine. Nevertheless, the organization opposed the issuance of patents for trivial evergreening. The majority of individuals contended that the report facilitated most evergreening methods. Furthermore, the report supported the issuance of patents for microorganisms to enhance the compatibility of the Indian Patents Act with the TRIPS agreement. In mid-February 2007, the report was retracted after it was revealed that a segment of the study had been plagiarized verbatim from a document published by a UK-based organization funded by the pharmaceutical industry. In March 2007, the government requested the Mashelkar committee to revise and resubmit its criticized report.

Similarly, the Patents Act does not delineate the requisite level of originality for the new molecule; thus, the patent approval procedure entails a degree of subjectivity. Considering this, the pharmaceutical industry fears that the authorities responsible for granting patents may lack the requisite qualifications to understand the complexities of molecular behavior essential for justifying novelty and, subsequently, the issuance of a patent.

**Challenges in Generic Pharma Industries**

The domestic pharmaceutical business is mostly a "branded generics" market, where pharmaceutical companies “sell off-patented pharmaceuticals under their own brand names, and the prices of these drugs differ from one rival to another. Branding and marketing efforts are still vital to pharmaceutical businesses' sales strategies, especially since the quality and testing standards in the pharmaceutical industry are not as strict as those in other regulated markets, such as the United States. Pharmaceutical businesses in India have large sales teams that reach out to doctors, who are the main decision-makers in a situation where insurance coverage is poor.

Most of the biggest pharmaceutical businesses in India have better credit profiles since they are present in the domestic pharmaceutical industry. This is due to the fact that they have a healthy long-term growth potential, sufficient profitability, and the advantage of diversification. Indian pharmaceutical companies will be negatively impacted by a significant decrease in the market share of branded generics, as the average prices will drop significantly and will outweigh any

potential gains from lower marketing expenditures. That so, we believe that the new criteria will not likely cause a quick transition away from branded generic[39]s. The implementation will face practical hurdles since the less strict drug quality standards in India could result in differences in drug quality and effectiveness among different producers. The requirement could change the decision-making process for the selection of a drug manufacturer from doctors to chemists, who may not have the necessary qualifications or may not prioritise the safety and effectiveness of the medication for patients. The government has already received a request from a national association of Indian physicians to postpone the new standards. The association has cited the difficulties that the new rules will create for clinicians in their efforts to ensure that patients receive safe and effective care. The most recent rules are part of the government's efforts to make healthcare more affordable by encouraging the use of unbranded generic medications, which can cost up to 80% to 90% less than their branded counterparts in some situations. The initiatives, which include establishing a nationwide chain of pharmacy outlets that focus on generic medications, have contributed to an increase in the sales share of trade generics, or medications that are dispensed without the involvement of a physician. Branded generics still make up more than 75% of the market share by volume and 90% by value[40]. This is due to worries about the ability to provide continuous service and maintain quality, which have restricted their growth in non-rural regions in India.

**i. Everything related to the price tag**

The pricing pressures that are imposed on marketed generics and biosimilars are still rather high. The key contributors are reimbursement restrictions and regulations in Europe and the rest of the world, as well as accelerated biosimilar launch price erosion due to the stronger and faster adoption of biosimilars. One paper describes how, in instances with five or more competitors, a 70 percent decrease can be reached relatively quickly". IGBA states that if these elements are not controlled appropriately, they could create an unfavourable economic climate for these products and drastically reduce the supply and access to important products.

**ii. Jumping through regulatory hoops**

The whitepaper states that there are still regulatory barriers preventing complex generics from entering the market, even in developed countries. These barriers include the amount of evidence needed to get products approved in areas such as respiratory and long-acting injectables, as well as the requirement for market-specific reference samples in key geographic regions. The costs of clinical trials for biosimilars are still significant,

[39] https://www.epw.in/engage/article/pharmaceutical-patents-public-health-and-pandemic

[40] https://www.fitchratings.com/research/corporate-finance/indias-generic-drug-prescription-mandate-faces-challenges-24-08-2023

which means that developers and manufacturers face a high level of risk. Additionally, some emerging markets have regulatory processes that are flawed, which slows down product development. These flaws include complicated approval processes and a lack of clarity regarding clinical study design. According to IGBA, it is essential to simplify the regulatory guidance in order to facilitate faster product development.

**iii. Unstable Supply**

The COVID-19 pandemic exposed the weaknesses in supply chains, especially the sources of active pharmaceutical ingredients (APIs) and key starting materials (KSMs). The white paper warns that the efforts of various governments to address these weaknesses—by relocating manufacturing to their own countries or developing local manufacturing capabilities—could lead to protectionism. This would increase costs for both companies and patients, which would harm overall product access and economic viability. Furthermore, IGBA stated that sustainability pressures will have an effect on supply chains as businesses are being asked to cut down on greenhouse gas emissions and waste. According to the report, it will be essential to balance global and local supply, as well as quality and environmental criteria, in the future.

iv. **New methods bring about new challenges**.

The introduction of new technologies in the pipeline is making products more complicated and raising the risk of investments at the same time, even as it allows for growth. The whitepaper emphasises that the introduction of new modalities, such as cell and gene therapies, will necessitate a new set of skills and, as a result, a significant amount of investment.

**v. Emerging markets: an obstacle to progress**

According to the International Generic and Biosimilar Medicines Association (IGBA), generic and biosimilar companies face significant obstacles in emerging markets because to competition and the structure of the market. It is difficult for players to establish their presence in local markets because of the competitive nature of these markets. Additionally, the effort is made even more challenging by factors such as the push to localise manufacturing, rising price controls, and inconsistent regulatory requirements. Furthermore, currency fluctuations can hinder growth, making the markets less appealing and restricting their expansion. The whitepaper states that traditional expansion techniques, including as collaborations, mergers, and acquisitions, have also produced inconsistent results, which has limited player engagement in these areas. According to the IGBA's analysis, foreign businesses must choose their target countries with care and take a focused portfolio approach if they want to attract

business from local players that are familiar with the market dynamics and avoid expensive growth efforts.

**Defences against Exorbitant Pricing and Unavailability**

1. Collaborations: Multinational pharmaceutical corporations exhibit a feeble presence in India; their portfolio of medications is restricted, their marketing infrastructure is inadequate, and their domestic activities are constrained. Multinational corporations may require partnerships with Indian firms for efficient marketing. This may lead to increased affordability for Indian patients. Evidence exists that Indian and global corporations are investigating prospects for reciprocal advantages. Nonetheless, it is improbable that the prices of future pharmaceuticals will match the existing affordability experienced by the Indian populace.

2. Compulsory licensing: The Indian government has retained the authority for compulsory licensing, allowing Indian companies the privilege to manufacture and market a drug prior to the expiration of the patent for that drug. Compulsory licensing will be implemented if the patent holder fails to provide the drug to Indian patients or if the price is prohibitively high for them. Compulsory licensing for export will similarly be utilized to provide medications to impoverished nations to address their pressing public health issues, in accordance with the TRIPS agreement of the Doha Declaration on Public Health.
3. The Brazilian Government has declared its intention to revoke the patent on many retroviral medications to avert the financial collapse of its effective public health program that offers free medication to HIV/AIDS patients.
4. Article 31 of the TRIPS agreement provides for "compulsory licensing without the authorization of the patent holder in the case of a national emergency or other circumstances of extreme importance or in cases of public, noncommercial use.[41] This idea is also embodied in Section 92 of the Indian Patents Act of 1970[42]. It is, however, uncertain that circumstances will arise which will make the Indian Government resort to compulsory licensing for psychotropic medication.

    a) If compulsory licensing is to succeed, some absurdities in the existent Patent Act require to be removed. One absurdity is that a compulsory license cannot be awarded during the first three years of the grant of a patent. Another absurdity is that the applicant for a compulsory license is required to state the nature of his interest in the matter and the existing patent holder is allowed to oppose the grant of the application. While this

[41] Article 31
[42] Section 92, of the Patents Act, 1970

is correct on the grounds of natural justice, it defeats the needs of emergency licensing. A third absurdity is that compulsory licensing is possible only for drugs which are patented in the country and not for those which are patented elsewhere. Pharmaceutical companies can therefore avoid compulsory licensing if they do not apply for a patent in India.

b) According to the provisions of the Patents Act of 2005, generic versions of patented drugs will be permitted to be manufactured and exported under a compulsory license to meet the major health needs of underdeveloped countries if the concerned countries issue a notification that the drug is required for the purpose.

c) Price control: The Indian Government has a list of drugs under price control. The exercise of this option may protect patients against exorbitant pricing. However, this option is unlikely to be exercised for newer psychotropic drugs unless the drugs have dramatic health benefits".

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